14-1354-cv

United States Court of Appeals

for the

Second Circuit

SUSAN SIMON,

Plaintiff-Appellant,

– v. –

SMITH & NEPHEW, INC.,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR PLAINTIFF-APPELLANT

JULIEN & SCHLESINGER, P.C.
Attorneys for Plaintiff-Appellant
207 East 94th Street, Suite 303
New York, New York 10128
(212) 962-8020

Table of Contents

TABLE OF AUTHORITIES

Cases **Pages**

Statutes

Other Authorities

JURISDICTION

Pursuant to 28 U.S.C. §1446, defendant Smith & Nephew, Inc. filed a Notice of Removal and plaintiff SUSAN SIMON's claims, originally filed in the Supreme Court of the State Court of New York, County of New York, were removed to the United States District Court for the Southern District of New York. The District Court had diversity jurisdiction over this matter pursuant to 28 U.S.C. §1332.

By Opinion and Order of Judge Paul A. Engelmayer, entered on December 3, 2013, defendant SMITH & NEPHEW, INC.'s Motion to Dismiss was granted and final judgment entered. Pursuant to F.R.A.P. Rule 4(a)(4), plaintiff filed a Motion for Reconsideration, thereby staying the final judgment. By Opinion and Order dated March 26, 2014, Judge Paul A. Engelmayer denied plaintiff Susan Simon's Motion for Reconsideration and a final judgment was thereby entered.

Plaintiff timely filed a Notice of Appeal on April 24, 2014. This Court has proper jurisdiction pursuant to 28 U.S.C. §1291.

STATEMENT OF THE ISSUES PRESENTED & STANDARD OF REVIEW

Issues Presented

1. Did the District Court err in finding that plaintiff failed to state a claim for strict products liability-design defect, negligence and breach of implied warranty in accordance with federal pleading standards and Fed. R. Civ. P. 12(b)(6)?

2. Did the District Court improperly find that defendant can rely upon the federal preemption doctrine pursuant to the Medical Device Amendment of 1976 (MDA) to preempt plaintiff's claims where plaintiff alleged facts that she was caused to suffer injury by the R3 Acetabular System, including the optional metal liner or R3 metal liner, a hip replacement device which was not examined and approved through the rigorous and strict standards provided for in the premarket approval process of the FDA?

3. Did the District Court err in denying plaintiff's request for leave to amend her complaint pursuant to Fed. R. Civ. P. 15 (a)(2)?

Standard of Review

1. This Court reviews *de novo* the District Court's grant of defendant's motion to dismiss for failure to state a claim. Specifically, "this court reviews de novo a district court's dismissal of a complaint pursuant to Rule 12(b)(6), 'construing the complaint liberally, accepting all factual allegations in

the complaint as true, and drawing all reasonable inferences in the plaintiffs' favor.'" *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152 (2d Cir. 2002); see also *E & L Consulting, Ltd. v. Doman Indus.*, 472 F.3d 23, 28 (2d Cir. 2006); *Panther Partners Inc. v. Ikanos Communs., Inc.*, 347 Fed. Appx. 617 (2d Cir. N.Y. 2009).

2. This Court reviews *de novo* the District Court's finding that plaintiff's strict liability-design defect, negligent, and breach of implied warranty claims are preempted. The R3 Acetabular System, including the optional metal liner or R3 metal liner component, and a femoral head component, which was implanted into plaintiff is not afforded the protection of a PMA approved device because the complete system as implanted into plaintiff was a Class II medical device that was not subject to the rigorous premarket approval and oversight of the FDA.

3. This Court reviews the District Court's denial of plaintiff's request for leave to amend her complaint under an "abuse of discretion" standard. *Panther Partners Inc.*, 347 Fed. Appx. 617. A district court has "abuse[d] its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence." *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990).

STATEMENT OF THE CASE

The underlying action arises in strict products liability-design defect, negligence, and breach of implied warranty claims arising out the plaintiff's injuries directly caused by defendant Smith & Nephew's R3 Acetabular System, including a Smith & Nephew optional metal liner component, or R3 metal liner component, [1] and Smith & Nephew femoral head component. [2] This hip replacement system, namely the R3 Acetabular System was implanted into plaintiff on February 16, 2010 and subsequently removed and replaced during a necessary revision procedure on May 29, 2013. Plaintiff initially commenced an action in the Supreme Court of New York, County of New York. Defendant removed the action to the Southern District of New York based upon diversity jurisdiction. (Doc. 1). [3] In light of the defendant's removal, plaintiff was afforded the opportunity to file an Amended Complaint that complied with federal pleading requirements. Prior to the service of an answer or any discovery in the action, defendant Smith &

[1] The term "optional metal liner component" as used in plaintiff's Amended Complaint is also identified as the "R3 metal liner." The use of both the "optional metal liner component" and the "R3 metal liner" are meant to refer to the same liner component at issue and used in plaintiff's hip replacement surgery in conjunction with the R3 Acetabular System.

[2] Plaintiff's claims relate specifically to the R3 Acetabular System that was implanted into the plaintiff Susan Simon during her hip replacement surgery. The medical device or system that plaintiff alleges caused injury is the R3 Acetabular System, including the optional metal liner component and femoral head component.

[3] Doc. 1 is a reference to the District Court docket number that was filed via the CM/ECF system in the Southern District of New York. Future references to "Doc. #" can be found on the CM/ECF docket for the District Court's proceedings.

Nephew, Inc. filed a Motion to Dismiss plaintiff's Amended Complaint. (Doc. 15). Following oral argument, Judge Paul A. Engelmayer, by Opinion and Order, dismissed plaintiff's Amended Complaint finding that plaintiff failed to state a claim and that even if plaintiff stated a claim, her claims were preempted by the Medical Device Amendments Act. (A-103). Plaintiff filed a Motion for Reconsideration which Judge Engelmayer denied by written Opinion and Order on March 26, 2014. (A-120). This appeal ensues following a final determination by the U.S. District Court for the Southern District of New York.

SUMMARY OF ARGUMENT

As detailed more fully herein, plaintiff's Complaint sufficiently and adequately alleges claims for strict products liability- design defect, negligence, and breach of implied warranty in accordance with the pleading standards set forth in *Ashcroft v. Iqbal*, 556 U.S. 662 (U.S. 2009) and *Bell Atlantic Corp. v. Twombly*, 550, U.S. 544 (2007). Plaintiff adequately pled facts to make her claims plausible on their face and provide a reasonable expectation that discovery will reveal evidence to support those allegations. *Twombly*, 550 U.S. at 556. In viewing plaintiff's Complaint, the District Court was required to take all factual allegations as true and draw all reasonable inferences in plaintiff's favor. *Harris v. Mills*, 572 F. 3d 66 (2d Cir. N.Y. 2009). Plaintiff's complaint was pled with enough sufficiency to adequately put defendant Smith & Nephew on notice of the nature of

the claim." *Gale v. Smith & Nephew, Inc.*, No. 12 Civ. 3614, 2013 WL 563403, at *5-6 (S.D.N.Y. Feb. 13, 2013).

Secondly, plaintiff's well pled claims for strict products liability- design defect, negligence and breach of implied warranty are not preempted under the Medical Device Amendments Act of 1976, 21 U.S.C. §360(c) ("MDA") as they relate to the R3 Acetabular System, which included an optional metal liner or R3 metal liner component, at the time it was implanted into the plaintiff/appellant. The R3 Acetabular System is a hip replacement system that was approved via the less stringent, 510(k) approval process. Smith & Nephew's later inclusion, marketing, design and distribution of the R3 metal liner as a component of the R3 Acetabular System which was implanted into plaintiff was not tested pursuant to the rigorous procedures set forth by the FDA to ensure its safety and effectiveness. As such, the R3 Acetabular System, including the optional metal liner, is not a medical device that is afforded the protection of federal preemption.

Lastly, plaintiff/appellant Susan Simon's request for leave to amend her complaint should have been granted by the District Court. Leave to amend should be freely and liberally granted provided there is no undue prejudice to the other side and that an amendment would not be futile. *Ruotolo v. City of N.Y.*, 514 F.3d 184, 191 (2d Cir. 2008). Allowing plaintiff to amend her complaint would not be futile as the allegations contained in the Complaint suggest that plaintiff's claims

can be plausibly replead with more specificity. Furthermore, the limited discovery and information obtained throughout motion practice in this matter would enable plaintiff to replead her actions with more specificity. While plaintiff already filed an Amended Complaint, that complaint was the only complaint filed in accordance with federal pleading standards. In the interests of justice, plaintiff should be granted leave to amend her claims against Smith & Nephew to plead her claims with specificity. Fed. R. Civ. P. 15(a)(2).

STATEMENT OF FACTS

Plaintiff/Appellant Susan Simon's Surgery

Plaintiff/appellant Susan Simon underwent left total hip replacement whereby a Smith & Nephew R3 Acetabular System, including a Smith & Nephew optional metal liner component, and Smith & Nephew femoral head component, were implanted into her left hip on February 16, 2010. (A-16). The surgery was performed utilizing the Smith & Nephew R3 Acetabular System, including, a Smith & Nephew three hole hemispherical acetabular shell (a 50mm outer diameter shell with three holes); the optional metal liner component of the R3 Acetabular System made of cobalt and chromium (identified as R3 38MM ID US CoCr LNR 50MM; part no. 71341150); and Smith & Nephew femoral head

component (identified as product no. 74122538; size 38 mm). (A-16).[4] Following plaintiff's left total hip replacement, she began to experience instability of the joint, a clicking sensation, locking, and radiating pain down her groin. (A-16). Plaintiff's doctor noted that her serum chromium and cobalt levels were elevated well above normal, acceptable levels. (A-16). On March 8, 2013, plaintiff had a serum cobalt level of 32 and a serum chromium level of 5.4. (A-17). Her doctor indicated that radiographs taken demonstrated a failed total hip replacement due to taper corrosion and metal wear. (A-17). Plaintiff was diagnosed with a metal-on-metal prosthesis reaction. (A-17). Her doctor concluded that the hip pain and clicking sensation were the result of corrosion and metal wear of the prosthesis. (A-17). On May 29, 2013, plaintiff underwent revision surgery with the exchange of liners and femoral head to eliminate any source of cobalt or chromium. (A-17). Plaintiff's doctor removed the Smith & Nephew optional metal liner component of the R3 Acetabular System made of cobalt and chromium (identified as R3 38MM ID US CoCr LNR 50MM; part no. 71341150) and the Smith & Nephew femoral head component (identified as product no. 74122538; size 38 mm). A Smith & Nephew R3 ultra-high molecular weight polyethylene acetabular liner and a Smith

[4] The three components utilized in plaintiff Susan Simon's hip replacement, namely the shell, R3 metal liner and femoral head component, are all required to accomplish a total hip replacement with Smith & Nephew's R3 Acetabular System. Without a shell, a liner and a femoral head, a total hip replacement is not possible.

& Nephew Oxinium femoral head were implanted during plaintiff's revision procedure. (A-17).

Regulatory History

The MDA is a federal regulatory scheme that governs FDA approved medical devices. 21 U.S.C.S. §301 *et seq.* Medical devices are categorized into three classes by the FDA based upon the risk that they pose to the public and greater oversight is provided for devices in the highest risk classification level, Class III. A medical device is Class III if it cannot be established that a less stringent classification would provide reasonable assurances of safety and effectiveness, and the device is purported or represented to be for a use in supporting or sustaining human life. 21 U.S.C.S. §360 (c)(1)(C)(ii)).

Class II devices are defined under the MDA as follows:

> Those which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360 (k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. 21 U.S.C.A. §360c (a) (1) (B)

Class II and Class III medical devices are subject to different approval procedures and oversight by the FDA. Class II medical devices are not subject to the same rigorous premarket approval and oversight by the FDA, and as such are not expressly preempted pursuant to the MDA.

Section 360k(a) provides that state-law causes of action against manufacturers of Class III medical devices are expressly preempted to the extent that they impose requirements different from, or in addition to, the requirements of federal law. Express preemption is defined in Section 360k(a) of the MDA, as follows:

> No state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C.S. § 360k(a).

Once a medical device has received premarket approval, the MDA in accordance with 21 U.S.C.S. § 360c et seq., forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. 21 U.S.C.S. § 360e (d)(6)(A)(i). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial

application. 21 U.S.C.S. § 360e (d)(6); 21 C.F.R. § 814.39(c). Device manufacturers also must obtain supplemental premarket approval or supplemental PMA, for any change to "design specification, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." 21 U.S.C.S. § 360e (d)(6)(A)(i). (A-106).

History of the Plaintiff's Prosthetic Device

Defendant/appellee Smith & Nephew, Inc. is a corporation engaged in the production, marketing, design, distribution, manufacturing, labeling and selling of medical devices. (A-15). Smith & Nephew designed, manufactured, distributed, sold, labeled, created and marketed the R3 Acetabular System. (A-13). The R3 Acetabular System is a total hip replacement system and is classified as a Type II medical device. (A-14). A total hip replacement requires the replacement of the patient's acetabulum and femoral head with a prosthetic shell, liner and femoral head.

The R3 Acetabular System was first submitted to the FDA for 510(k) premarket notification pursuant to 21 U.S.C. §360(k) on or about May 10, 2007 under submission number K070756. (A-15). This 510(k) submission is different than the premarket procedures set forth above and do not require that the manufacturer submit clinical testing or studies to the FDA prior to approval. The 510(k) summary for the R3 Acetabular System and its relevant components

indicated that the system was *substantially equivalent* to predicate devices approved by the FDA. (A-15; A-56) Smith & Nephew received clearance for the R3 Acetabular System from the FDA pursuant to submission number K070756 on June 6, 2007. (A-15; A-56) The R3 Acetabular System includes a class of components that must be utilized together in conformity to accomplish a total hip replacement system. These components are a shell, a liner, and a femoral head. A femoral head component is necessary in all hip replacements. (A-69). The femoral head fits into the metal liner. (A-69) The 510(k) identifies only one shell and one liner, but following the initial 510(k) submission, Smith & Nephew added additional components that could be used within the R3 Acetabular System, including the R3 metal liner.

The optional metal liner or R3 metal liner component, utilized in plaintiff's surgery was introduced by Smith & Nephew into the R3 Acetabular System on or about February 27, 2009. (A-15). A press release was issued whereby Smith & Nephew notified the public and medical community of the introduction of the R3 metal liner as a component of the R3 Acetabular System. (Doc. 49, Ex. A) [5] The R3 metal liner was originally approved for use as a component of the Birmingham Hip Resurfacing (BHR) System, a hip resurfacing system, in contrast to the R3

[5] The reference to Doc. 49 refers to the S.D.N.Y. Docket sheet for documents that were filed via ECF. Further reference to "Doc. #" refers this Court to the S.D.N.Y. Docket sheet.

Acetabular System, a hip replacement system.[6] (A-15). Smith & Nephew's inclusion, marketing, design and distribution of the R3 metal liner as a component of the R3 Acetabular System, was not required to undergo FDA review to ensure its safety and effectiveness as required by devices that are subject to PMA approval. Nor did the R3 Acetabular System including the optional metal liner or R3 metal liner component undergo additional testing to ensure that the inclusion of a component from the BHR System was safe in this device.

On June 1, 2012, Smith & Nephew issued a voluntary recall of the component, which Smith & Nephew described in its notice as the R3 metal liner component of the R3 Acetabular System. (A-65). In this Smith & Nephew notice, Smith & Nephew states that "we are taking the precautionary step of withdrawing the optional metal liner within the R3 Acetabular System from the market." (A-65). The notice states that "the company has chosen to withdraw the optional metal liner component within the R3 Acetabular System as a precautionary measure following a review of the most recent data." **(A-65).** The urgent field safety notice was released by Smith & Nephew to the medical community

[6] The R3 Acetabular System is a hip replacement system. A hip replacement system is the complete replacement of the damaged joints, and as stated in oral argument, the femur is being replaced. (A-86) The BHR System is a hip resurfacing system. As explained in oral argument, a hip resurfacing system is "just the acetabular socket and the femoral component. They don't replace the femur." (A-84)

explaining the recall and follow up procedures for those individuals that were implanted with the R3 Acetabular System including the R3 metal liner component. (A-65). In addition to the notice issued by Smith & Nephew, the FDA released a statement on its website regarding the recall of the Smith & Nephew R3 metal liners of the R3 Acetabular System. (A-64). The FDA indicated that "the R3 Acetabular System is a total hip replacement system component that is not cleared for use with the R3 metal liner." (A-64). The FDA's notice further states that the R3 metal liner was being withdrawn by Smith & Nephew due to higher than expected revision surgeries. (A-64). Furthermore, despite Smith & Nephew's promotion and marketing of the use of the optional metal liner as a component of the R3 Acetabular System during hip replacement surgeries, including plaintiff's surgery, the statement on the FDA website indicates that "the R3 metal liner is only approved for use with the Birmingham Hip Resurfacing System." (A-64).

ARGUMENT

I. Plaintiff's Amended Complaint was sufficiently pled and it was error to dismiss her complaint for failure to state a claim

The District Court erred in granting defendant's Motion to Dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure Rule 12 (b) (6). This Court reviews the District Court's decision *de novo,* reviewing the legal sufficiency of the complaint, taking all factual allegations as true and drawing reasonable inferences in plaintiff's favor. *Harris*, 572 F.3d 66.

The Supreme Court set forth standards for determining the sufficiency of a complaint in the *Iqbal* and *Twombly* cases. A well-pled complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. 662 (quoting *Twombly*, 550 U.S. at 570; see also *Harris*, 572 F.3d at 71-72.) To be plausible, the complaint need not show a probability of plaintiff's success, but it must evidence more than a mere possibility of a right to relief. *Id* at 678. "Determining whether a complaint states a plausible claim for relief will…be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id*.

Plaintiff Susan Simon's Amended Complaint alleges strict products liability-design defect, negligence, and breach of implied warranty claims against Smith & Nephew for the injuries caused by the R3 Acetabular System, including an optional metal liner or R3 metal liner, and a femoral head component, when it was utilized in plaintiff's total hip replacement surgery.

In the context of determining the sufficiency of a complaint, "a plaintiff's pleading burden should be commensurate with the amount of information available to them." *Bausch v. Stryker Corp.*, 630 F.3d 546, 560 (7th Cir. 2010). Additionally, courts have found that valuable information is kept confidential as a matter of federal law and formal discovery may be required before a plaintiff can be fairly expected to identify specific defects." *Bausch*,630 F.3d at 560. The

specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery. *Id.* Because there has been no discovery in this action, the District Court should have taken into consideration that valuable information related to the FDA's review and approval of the R3 Acetabular System are kept confidential and formal discovery may be required for the plaintiff to identify specific defects when reviewing the sufficiency of plaintiff's complaint. Additionally, Smith & Nephew's internal documents regarding the decision to introduce the R3 metal liner as a component of the R3 Acetabular System are not readily available. Plaintiff factually pled that Smith & Nephew introduced the R3 optional metal liner into the R3 Acetabular System. (A-15). Based upon this allegation, plaintiff sufficiently pled facts that linked Smith & Nephew with the decision to design the R3 Acetabular System with an optional metal liner component or R3 metal liner, and therefore allowed a metal on metal interaction to take place. Plaintiff's complaint alleged sufficient facts that make her claims plausible with respect to the R3 Acetabular System which she identified was the cause of her injuries, and plaintiff raised a reasonable expectation that discovery will reveal evidence to further support the plaintiff's allegations.

The District Court incorrectly focused only on the original 510(k) submission of the R3 Acetabular System that did not include the R3 metal liner and ignored the fact that Smith & Nephew later acknowledges in their own recall notice that it introduced, marketed and designed the metal liner as a component of the R3 Acetabular System. (A-65). Furthermore, the subsequent statement of Smith & Nephew indicating the company's withdrawal of the R3 metal liner from the R3 Acetabular System is clear evidence that the optional metal liner was marketed and designed by Smith & Nephew as a component for use with R3 Acetabular System following the initial 510(k) approval. (A-65). Based on the foregoing, the District Court erred in dismissing plaintiff's complaint.

A. Claim for Strict Products Liability-Design Defect

Plaintiff adequately stated a claim for strict products liability under a design defect theory. In order to state a claim for strict products liability under a design defect theory in New York, a plaintiff must allege that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001). Courts of this State have determined that "the proper standard to be applied should be whether the product as designed was 'not reasonably safe'—that is, whether it is a product which, if the design defect were known at the time of

manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner." *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 108 (N.Y. 1983). "A manufacturer is held liable regardless of his lack of actual knowledge of the condition of the product because he is in the superior position to discovery any design defects and alter the design before making the product available to the public." *Voss*, 59 N.Y.2d at 107.

Plaintiff's design defect claim relates specifically to the R3 Acetabular System that was utilized in plaintiff Susan Simon's hip replacement surgery. The surgery was performed utilizing the R3 Acetabular System, including the optional metal liner component, and a femoral head component. Plaintiff pled that the R3 Acetabular System was submitted to the FDA for 510(k) premarket notification on May 10, 2007 and that Smith & Nephew received clearance approval for the R3 Acetabular System on June 6, 2007 pursuant to submission number K070756. (A-16). Plaintiff pled that Smith & Nephew did not receive premarket approval for the R3 Acetabular System. (A-14). Plaintiff alleged that defendant designed, manufactured, distributed, sold labeled, created and marketed a femoral head component. As previously stated, a femoral head component is required to perform a total hip replacement and is an essential component to effectuate the use of the R3 Acetabular System. Plaintiff further alleged that defendant designed,

manufactured, distributed, sold labeled, created and marketed the optional metal liner component of the R3 Acetabular System. (A-15). There is factual evidence including the statements of Smith & Nephew in their notice of withdrawal, to confirm that the R3 metal liner and femoral head component, which plaintiff alleges to be the cause of her injuries, were necessary components of a hip replacement system that was designed, marketed and distributed by Smith Nephew. Furthermore, Smith & Nephew knew or should have known that when it introduced the optional metal liner or R3 metal liner component into the R3 Acetabular System, that the metal liner would be used in conjunction with a Smith & Nephew metal femoral head component. The optional metal liner removed during plaintiff's revision surgery was identified as R3 38MM ID US CoCr LNR 50MM; part number 71341150. (A-17). Smith & Nephew's voluntary recall of the optional metal liner component from the R3 Acetabular System is further proof that Smith & Nephew designed the R3 Acetabular System to include an optional metal liner component, that this system was defectively designed and caused plaintiff's injuries. This fact, along with Smith & Nephew's notice of market withdrawal of the optional metal liner component of the R3 Acetabular System confirms the accuracy of the plaintiff's allegations and serves as further support for plaintiff's claim that Smith & Nephew acted to design, market and distribute an R3 Acetabular System which included the R3 metal liner.

In her Complaint, plaintiff alleged that the R3 Acetabular System, including the optional metal liner component, and a femoral head component, as designed, marketed and distributed by Smith & Nephew posed a substantial likelihood of harm. Plaintiff alleged that the specific harm caused by this R3 Acetabular System, as follows: "its propensity to deteriorate prematurely and release cobalt and chromium into the human body", and that the R3 Acetabluar System and relevant components that were utilized in Susan Simon's surgery, did in fact release cobalt and chromium into the human body and cause injury and the need for revision surgery. (A-15).

Plaintiff alleged facts in her Complaint that demonstrate that the R3 Acetabular System, including an optional metal liner, and a femoral head component, as designed, marketed and distributed by Smith & Nephew created an unreasonable risk of harm and caused injury to the plaintiff. Plaintiff clearly alleged specific injuries and side effects directly related to the defective product, including plaintiff's necessity to undergo revision surgery, increased levels of cobalt and chromium in her body causing metalosis, and the removal of the optional metal liner and femoral head components. Smith & Nephew acknowledged in their recall notice, that these injuries were reasonable bases for their decision to recall the R3 metal liner. These injuries were directly caused by the defective design of the R3 Acetabular System, including the optional metal

liner, and a femoral head component, which caused a metal on metal reaction when utilized together. Smith & Nephew knew or should have known of the propensity for a metal on metal interaction when it introduced the R3 metal liner into the R3 Acetabular System when used with a metal femoral head component which was certainly foreseeable. Plaintiff has pled concrete injuries and side effects that are directly related to Smith & Nephew's decision to design and market the R3 Acetabular System to include a metal liner component in February 2009. Plaintiff pled more than "various side effects" and conclusory damages caused by the defectively designed product. *Lewis v. Abbot Labs.,* No. 08 Civ. 7480, 2009 WL 2231701, at 4 (S.D.N.Y. July 24, 2009). Plaintiff has set forth sufficient and substantiated facts that rise above a mere possibility that establish that the R3 Acetabular System, including the R3 metal liner, and a femoral head component, was defectively designed, marketed and distributed by Smith & Nephew and was a substantial factor in causing plaintiff's injuries.

Plaintiff clearly and succinctly demonstrated that safer, alternative designs existed that would not have rendered the R3 Acetabular System defective and which did not pose a substantial likelihood of harm. Plaintiff alleged that it was feasible for defendant Smith & Nephew to design the R3 Acetabular System in a safer manner. (A-24) The relevant case law states that the "plaintiff must show that a safer alternative design was actually available at the time of the sale, and not

merely that a safer design was theoretically feasible." *Adams v. Genie Indus., Inc.*, 14 N.Y.3d 535, 538 (N.Y. 2010). Here, plaintiff alleged that safer alternative designs existed at the time plaintiff had her surgery and defendant acknowledges that the R3 Acetabular System originally submitted to the FDA for 510(k) approval was an alternative design. Another safe, alternative design alleged by plaintiff are those non metal-on-metal total hip replacement systems designed by both Smith & Nephew and other devices manufacturers, such as Zimmer, Stryker and DePuy, or the Smith & Nephew R3 liner utilized in plaintiff's revision surgery. (A-26, 27)

The R3 Acetabular System was designed as a hip replacement system that was designed to provide patients with the flexibility to tailor the implant to each patient's requirements. (A-13). In designing and marketing the R3 Acetabular System, Smith & Nephew was in the best position to test the product and any additional components that were designed, marketed and distributed to be utilized with the product, specifically the R3 metal liner, to ensure that the product would function as a hip replacement before it was made available to the public. The recall notice released by Smith & Nephew clearly demonstrates that the R3 Acetabular System including the optional metal liner component was defectively designed and did not function as a reasonable person would expect. Even if Smith & Nephew did not have actual knowledge of the defects in the R3 Acetabular System including the optional metal liner at the time of manufacture and

distribution, as the device manufacturer, Smith & Nephew should be held liable pursuant to the laws of the State of New York. *See Voss*, 59 N.Y.2d 102.

Plaintiff sufficiently pled facts to place defendant on notice that the R3 Acetabular System, including the optional metal liner, and a femoral head component, implanted into plaintiff was defectively designed, marketed and distributed due to its propensity to deteriorate prematurely and release cobalt and chromium into the human body, that this defective design was a substantial factor in causing plaintiff's injuries and that there was a feasible safe alternative design, including the Smith & Nephew product later utilized during her revision surgery. As such, plaintiff has sufficiently pled a design defect claim and it was error for the District Court to dismiss plaintiff's complaint.

B. Claim for Negligence

Plaintiff adequately pled a claim for negligence and it was error for the District Court to dismiss her claims. In order to make out a *prima facie* case of negligence in New York, "plaintiff must show 1) that the manufacturer owed plaintiff a duty to exercise reasonable care; 2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, *i.e.* reasonably certain to be dangerous; 3) that the defect was the proximate cause of plaintiff's injury; and 4) loss or damage. *Lewis*, 2009 WL 2231701, at 4 (citing *Colon*, 199 F. Supp. 2d at 82-83**.**

Plaintiff alleged that Smith & Nephew is a company engaged in the business of designing, manufacturing and selling medical devices, including hip replacement systems, including the R3 Acetabular System. Plaintiff further alleged thatSmith & Nephew negligently designed the R3 Acetabular System, to include an optional metal liner component, and that as a result of the negligent design, plaintiff was implanted with the product and was caused to experience harm directly related to the negligent design.

Plaintiff sufficiently pled that Smith & Nephew's R3 Acetabular System, including optional metal liner, and a femoral head component, was dangerous and defective as designed. Plaintiff's claims are supported with specific facts, *i.e.*, "the construction and design of the optional metal liner which was made of Cobalt and Chromium, was caused to deteriorate and breakdown, thus causing plaintiff to experience increased levels of Cobalt and Chromium in her bloodstream as a direct result of the implantation of defendant's device. (A-15-16). Plaintiff further alleged that Smith & Nephew was negligent in "failing to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the R3 Acetabular System, and its components, specifically the optional metal liner component and femoral head component into the interstate commerce in that defendant knew or should have known that using the R3 Acetabular System, and

its components, including the optional metal liner component and femoral head component created a high risk of unreasonable and dangerous side effects, including but not limited to severe pain and suffering, loss of mobility, metalosis, difficulty sitting, radiating pain in her groin, constant clicking and locking of the R3 Acetabular System, the need for additional surgery to repair, remove and/or replace the optional metal liner component and femoral head component." (A-19). Plaintiff further alleged that Smith & Nephew's negligence included "not conducting sufficient testing programs to determine whether the aforesaid R3 Acetabular System was safe for use…selling the R3 Acetabular System without making proper and sufficient tests to determine the dangers to recipients…negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and/or the FDA of the dangers of the R3 Acetabular System; negligently failing to recall its dangerous and defective R3 Acetabular System at the earliest date that it became known to Smith & Nephew that said R3 Acetabular System was, in fact, dangerous and defective…negligently advertising and recommending the use of the aforesaid R3 Acetabular System without sufficient knowledge as to its dangerous propensities…negligently representing that the R3 Acetabular System had equivalent safety and efficacy as other, non-defective total hip replacement systems…failing to advise relevant information to the Plaintiff, health care professionals, hospitals and/or the FDA,

concerning the severity of risks and dangers of the R3 Acetabular System; failing to properly warn and instruct regarding the increased frequency and severity of adverse events occurring with the R3 Acetabular System." (A-20).

Plaintiff's allegationthat Smith & Nephew did not conduct sufficient testing prior to the introduction of the optional metal liner or R3 metal liner as a component of the R3 Acetabular System to determine if the newly designed system was safe for use is supported by the fact that the optional metal liner was voluntarily withdrawn from use as a component within the R3 Acetabular System within a year after it was introduced. (A-65). There is no evidence that testing was conducted by either by Smith & Nephew or by the FDA prior to Smith & Nephew's introduction of the R3 metal liner as a component of the R3 Acetabular System to determine any potential risks or dangers, prior to its distribution into the marketplace and its use in patient's hip replacement surgeries. Additionally, since the R3 metal liner was only found to be approved as a component of the BHR System, a hip resurfacing system, Smith & Nephew's decision to introduce, design, market and distribute the R3 metal liner as a component for use with the R3 Acetabular System, a hip replacement system, was never tested to assure its safety and effectiveness as is required for PMA approved devices.

Smith & Nephew's failure to adequately test and take reasonable care in designing, marketing, and distributing the R3 metal liner as a component for use

with the R3 Acetabular System was the proximate cause of plaintiff's injuries. Based upon the totality of plaintiff's allegations contained in her Amended Complaint, it was error for the District Court to dismiss her negligence claims.

C. Claim for Breach of implied warranty

To plead a claim for a breach of implied warranty under New York law, a plaintiff must prove that "(1) the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Lewis v. White*, 2010 WL 6465230(S.D.N.Y. July 1, 2010)(*citing In re American Export Lines, Inc.* 620 F. Supp. 490, 519 (S.D.N.Y. 1985) The "implied warranty is breached where the product in question is not fit for the ordinary purpose for which it is to be used." *Lewis*, 2010 WL 6465230 . (internal quotation marks omitted).

A design defect claim underlies a claim for breach of implied warranty, therefore, the Court is referred to the arguments advanced more completely as to the sufficiency and adequacy of plaintiff's design defect claim against Smith & Nephew. Based upon the sufficiency of plaintiff's design defect claim against Smith & Nephew, plaintiff has adequately pled an essential claim for her breach of implied warranty claim.

The defective condition of the R3 Acetabular System that was implanted into plaintiff existed at the time it was delivered to the ultimate user, Susan Simon. Smith & Nephew, a medical device manufacturer and distributor, caused the system to enter to stream of commerce. The R3 Acetabular System was intended to be used as a total hip replacement system and was warranted to the FDA and to the public to be safe, of a merchantable quality and fit for its intended purpose. (A-28) Plaintiff sufficiently alleged that the R3 Acetabular System was not fit for its intended purpose when utilized with the R3 metal liner. As illustrated, the defective condition is its propensity to deteriorate prematurely and release cobalt and chromium into the body; that it did in fact breakdown and release cobalt and chromium into plaintiff's body, causing the need for revision surgery; and thus was not fit for its intended purpose as a hip replacement device. As the manufacturer and designer of the product, Smith & Nephew had reason to know that designing the R3 Acetabular System with the R3 metal liner, which would potentially be used with a Smith & Nephew metal femoral head, would cause injury.

Plaintiff has pled concrete factual allegations that Smith & Nephew breached an implied warranty owed to plaintiff for the injuries caused by the R3 Acetabular System, which Smith & Nephew defectively designed to include an R3 metal liner, and directly caused plaintiff to suffer injuries.

II. Plaintiff's claims are Not preempted pursuant to Section 360k(a) of the MDA

The District Court erred in finding that plaintiff's claims for strict products liability-design defect, negligence and breach of implied warranty claims are preempted by the Medical Device Amendments Act. This Court reviews the District Court's finding *de novo*. The R3 Acetabular System, including the optional metal liner or R3 metal liner, is a hip replacement device which was not examined and approved through the rigorous and strict standards, is not subject to preemption pursuant to Section 360(k) of the MDA.

Plaintiff's claims are not subject to preemption pursuant to Section 360k (a) of the MDA because plaintiff's allegations relate to injuries caused by the R3 Acetabular System that was implanted and utilized during Susan Simon's surgery. Plaintiff's total hip replacement was performed utilizing a Smith & Nephew R3 Acetabular System, including the optional or R3 metal liner, and a femoral head component, which did not undergo rigorous testing or approval by the FDA to ensure its safety and effectiveness. The District Court erred in determining that plaintiff's claims were preempted based upon plaintiff's complaint, which clearly alleged that the R3 Acetabular System at issue was a Class II device that was not the subject of PMA approval and that following Smith & Nephew's introduction, design, marketing and distribution of the R3 metal liner as a component of the R3

Acetabular System, additional testing was not conducted of the R3 Acetabular System to give rise to the preemptive protection afforded by the MDA.

The purpose of the MDA is to shield and protect consumers from complex medical devices that posed a serious risk of being inadequately tested or improperly used or designed. *S. Rep. No. 94-33, 94th Cong., 2d Sess. (1976), reprinted in 1976 U.S. Code Cong. & Admin. News 1070, 1075.* Because the MDA provides for strict oversight and scrutiny of Class III medical devices only, those that pose the greatest risk to human life, Courts have held that state-common law tort claims regarding the safety and effectiveness of Class III devices are preempted. However, because only Class III medical devices are subject to the continuing oversight and scrutiny of the FDA, other medical devices, such as those in Class II, that are not subject to the same stringent standards, may be subject to state common law claims.

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court held that Class III medical devices approved through a PMA were expressly preempted by section 360k(a) of the MDA. In contrast to Class III medical devices which are required to undergo rigorous testing and review to assure safety, Class II medical devices do not undergo the same stringent approval process by the FDA prior to being released into the marketplace. As such, a device that did not receive premarket approval, such as the R3 Acetabular Sytem, would not be subject to the

continued rigorous oversight and the manufacturer would be allowed to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. *See* 21 U.S.C.S. § 360e (d)(6)(A)(i); *Riegel*, 552 U.S. 312. The safety and effectiveness of Class II medical devices, such as the R3 Acetabular System, has not been strictly warranted by the FDA, therefore preemption does not apply. The R3 Acetabular System did not undergo the rigorous testing or oversight by the FDA prior to being released into the marketplace by Smith & Nephew. Instead the R3 Acetabular System was approved via premarket notification procedures whereby it was determined by the FDA that it was substantially equivalent to medical devices that preceded its introduction.

As stated more completely in the arguments advanced regarding the sufficiency of each cause of action in her complaint, plaintiff's allegations address the complete medical device utilized in plaintiff's surgery; the R3 Acetabular System, including the optional metal liner or R3 metal liner, and a femoral head component which was designed, marketed and distributed by Smith & Nephew. The original R3 Acetabular System was approved by the FDA pursuant to 510(k) premarket notification and not the rigorous testing and oversight that applies to PMA approved devices. Following Smith & Nephew's introduction, design, marketing and distribution of the optional metal liner or R3 metal liner into the R3

Acetabular System, no additional testing or review was conducted by the FDA. As stated above, because the R3 Acetabular System was never subject to premarket approval, the rigorous oversight and applicability of the MDA never took effect. *See Riegel*, 552 U.S. 312.

The R3 Acetabular System, originally approved by the FDA through the 510(k) premarket notification process and later designed, marketed and distributed with an optional metal liner or R3 metal liner component, is not entitled to the protection of preemption based upon the assertion of defendant's counsel that the R3 metal liner received premarket approval or supplemental premarket approval by the FDA. The Supplemental PMA documents provided by Smith & Nephew purport to evidence that the R3 metal liner received approval for a line extension. (A-35, 38) Nothing contained in this document states that the Class II R3 Acetabular System underwent any testing or review regarding the safety of adding the R3 metal liner as a component within the R3 Acetabular System. The document annexed to the record as A-35 relates to the Birmingham Hip Resurfacing (BHR) System and is identified as PMA Number P040033 and Supplement Number S006 which is dated November 13, 2008. (A-35) This document identifies that it is a supplement and further states "approval for a line extension to the bhr system (ie., modular version of the bhr cup for uses with optional screws and apex/screw hold covers) and a side change (smith & nephew,

inc., memphis tennessesse)." (A-35) This document does not refer to the R3 metal liner or the R3 Acetabular System. Additionally, the document annexed to the record as A-38 also relates to the Birmingham Hip Resurfacing (BHR) System and is identified as PMA Number P040033 and Supplement Number S013 which is dated December 31, 2009. (A-38) This document states that the reason for the supplement is a process change in manufacturing. (A-38) The document states "approval for a change to new testing equipment used for measuring surface finish, tape angle, and diameter for the r3 metal liners." (A-38) Nothing in this document states that the R3 metal liners received supplemental PMA approval for use with the R3 Acetabular System. Furthermore, to the extent that these documents establish that the R3 metal liner received PMA approval for use with the BHR System, a hip resurfacing system, different testing protocol would be required to ensure the safety and effectiveness of the R3 metal liner when used in the R3 Acetabular System, which is a hip replacement system.

The use of a component of a separate device which received premarket approval does not confer the benefit and protections of premarket approval and preemption to the component when utilized in a different device, especially when the different device was not subject to premarket approval and would not be subject to preemption on its own. A Class II medical device that was approved via the 510(k) premarket notification procedures is not entitled to preemption based

solely upon its use of a component that was initially approved for use as a component of a different PMA device. If a specific component utilized within a medical device or system was subject to premarket approval for how it functioned in a specific device, when the component is used in a completely different medical device, i.e. a Class II medical device that was not subject to premarket approval, premarket approval and testing of the component does not transfer to the component itself when the component is used in a different device. The ramifications of the various methods of FDA review of medical devices as they pertain to a specific component of a product have been addressed by the Courts in various contexts.

In *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 780 (D. Minn. 2009), the Court examined claims related to a drug-eluting stent where the FDA had exercised its authority to regulate the product as a medical device. The Court noted that the Cypher stent is not merely a drug or merely a drug delivery system but rather a compound of mechanical and chemical parts that work together as a single medical device. The *Riley* Court reasoned that since plaintiff's claims were against the device as a whole, it made no sense and would probably be impossible to pick apart components of a medical device and apply different analyses to different components which in the instance of *Riley* would involve premarket approval of a

medical device as well as the implied preemption analysis that applies to claims relating to federally regulated drugs. The *Riley* Court noted:

> It makes no sense – indeed, it would probably be impossible – to pick apart the components of a medical device and apply different pre-emption analyses to different components. *Riley* at 780.

The integrated medical device, rather than its separate components, was the subject of FDA investigation to assure its safety.

In *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648 (S.D. Tex. 2010), the Court examined claims as they pertained to the Trident hip replacement system, a system that received PMA approval. The Trident system was comprised of components including an acetabular shell, which previously received § 510(k) approval and was commercially available, prior to its use in the Trident system that plaintiff received. Noting that despite the prior § 510(k) approval of the acetabular shell for another use, the acetabular shell component as it functioned in the Trident hip replacement system was subject to rigorous testing by the FDA along with other components of the Trident system as this system was examined for premarket approval, the Court declared:

> … that the acetabular shell was previously approved through only the § 510(k) process, and was commercially available when the Trident system was approved, does not change the fact that it was later subject to the more rigorous scrutiny of the PMA process as a component of the Trident system. Because the Trident system went through the PMA process, and the acetabular shell was

> part of this system, the first part of the Riegel test is satisfied. *Lewkut* at 657.

In *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466 (D. Mass. 2012), the Court examined the claims of product defect as they related to the insulin pump component of a device called the Paradigm Real Time System. This system was an integration of Medtronic products including a monitoring system which had received pre-market approval in 1999, and the insulin pumps which had been approved via the § 510(k) process in 2004. The manufacturer of the Paradigm Real Time System did not receive premarket approval for its integrated product simply because one of its components, the monitoring system, had previously received premarket approval as a separate and distinct device. Rather, the integrated product, the Paradigm Real Time System, which included components that had undergone different levels of FDA review, was the subject of a supplemental application which was approved by the FDA in 2006. The *Duggan* plaintiffs argued that since the pump component on its own had not received premarket approval prior to its integration into the final product that was the subject of premarket approval, their claims alleging a defect in the pump were not preempted. The *Duggan* Court held:

> Many Courts have held that once pre-market approval is granted, all claims related to all components of the device are preempted. See *Riley v. Cordis Corp*., 625 F. Supp 2d 769, 780 (D. Minn. 2009) ("It makes no sense – indeed, it would probably be impossible – to pick apart

> the components of a medical device and apply different preemption analyses to different components."); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 650 (S.D. Tex. 2010) ("[A]ttempting to separate the component parts of a medical device for purposes of preemption is not appropriate."). This analysis applies even where a component of a PMA-approved device had previously been approved through the § 510(k) process. *See id.* At 657 (concluding that the plaintiff's claims were preempted because prosthetic hip system went through PMA process, even though a component had been approved through less rigorous § 510(k) process). *Duggan at* 471.

However, an integrated product does not secure the benefit of preemption because one of its components had previously secured premarket approval. *Id.* Rather a device comprised of components which had undergone various degrees of review and oversight, must itself be submitted for premarket approval testing to ensure the safety and effectiveness of the device as a whole and obtain the protection of preemption. As these decisions demonstrate, when an entire product, system or device is examined in accordance with the rigorous standards of premarket approval, a separate review of each component is not undertaken by the FDA. Rather, the entire integrated product is tested and reviewed in accordance with FDA pre-market approval standards. The fact that individual components had previously been subject to the lesser 510(k) standard does not provide a basis to avoid pre-emption of a claim for injury related to that particular component as it functions within the integrated product. The premarket approval process is deemed

to determine that the product, comprised and configured of certain components, is safe.

The arguments advanced by defendant's counsel and the decision of the District Court improperly extend the rationale of these determinations of the Courts.When a component is initially reviewed and examined by the FDA in relation to its use within a Class III PMA approved device, the later integration of the component into a different device that was subject to the 510(k) standards does not carry a preemptive effect. Simply put, the fact that a product is carefully tested to assure that the product, including all of its necessary and integrated components is safe, does not establish that each individual component is safe for a different use on its own or utilized with other components in a completely different product. Even though the individual component may have undergone rigorous testing related to its risks and benefits within a PMA approved system, the use of the individual component on its own or in a different device is required to undergo rigorous testing to determine its safety and effectiveness in a wholly different product or system. Where injury is claimed to be caused by a component of a PMA approved device that is later integrated for use within a 510(k) approved system, a manufacturer cannot avoid the ramifications and seek the protection of preemption because the FDA did not warrant the safety and effectiveness of the later product as a whole.

The reasoning of the Courts in *Lewkut* and *Riley* does not support the converse reasoning or bring about the conclusion that a singular component of a different device which secures premarket approval can be independently entitled to protection when the device manufacturer decides to design and market the component in a completely different device that was subject to different testing standards and review. In fact, such a conclusion runs contrary to the reasoning and purpose of the preemptive protection provided for in the MDA.

As recognized by the Court in *Riegel*, premarket approval is specific to an individual medical device which must "be made with almost no deviations from the specification in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Reigel* at 323. In fact, once a medical device has received pre-market approval, the FDA in accordance with 21 U.S.C.S. § 360c et seq., forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. 21 U.S.C.S. § 360e (d)(6)(A)(i).

The R3 metal liner component utilized in the R3 Acetabular System that was implanted into plaintiff was initially designed, marketed and distributed by Smith & Nephew as a component of the BHR system, a separate Smith & Nephew device. The BHR system, which was a hip resurfacing system rather than a hip

replacement system, secured premarket approval and was tested to ensure its safety and effectiveness by the FDA. Following Smith & Nephew's decision to introduce, design, market and distribute the R3 metal liner as a component of the R3 Acetabular System, a hip replacement system as opposed to a hip resurfacing system, in February 2009, additional approval or testing was not undertaken by the FDA. As such, the integration of the R3 metal liner as a component of the R3 Acetabular System was not tested to ensure the safety and effectiveness of the system. Plaintiff Susan Simon's claims are not preempted by virtue of Smith & Nephew's decision to include, design, market and distribute the R3 metal liner from a wholly different Smith & Nephew device into the R3 Acetabular System which was not subject to premarket approval by the FDA.

Courts have determined that preemption analysis should not be defeated by the "off label" or "off market" use of a device or product by a medical professional. *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001). Here, plaintiff has not pled any "off label" or "off market" use of the R3 metal liner. Instead, plaintiff's complaint clearly evidences that Smith & Nephew introduced, designed, marketed and distributed the R3 metal liner to be used as a component of the R3 Acetabular System, a product for which defendant has not earned the benefit of preemptive protection. (A-16) This case does not give rise to an issue where "off label" or "off market" uses are applicable.

The use of the optional metal liner or R3 metal liner as a component of the R3 Acetabular System is not an off market or off label use that provides Smith & Nephew with the protection of federal preemption. Smith & Nephew introduced, designed, marketed and distributed the R3 metal liner as a component of the R3 Acetabular System. (A-16) Susan Simon's surgery was performed following Smith & Nephew's introduction, design, marketing, and distribution of the optional metal liner as a component of the R3 Acetabular System. The optional metal liner removed from plaintiff is etched with "R3," which is additional support that the optional metal liner was designed and marketed to be used with the R3 Acetabular System and that its use was not an independent decision of a physician without the approval of Smith & Nephew. Any finding that the use of the R3 metal liner with the R3 Acetabular System was off label or made at the sole discretion of a physician is unsupportable by the evidence or pleadings. Rather, as addressed herein, after the 510(k) approval of the R3 Acetabular System, Smith & Nephew introduced and marketed components, including the R3 metal liner for use with the R3 Acetabular System.

Plaintiff's claims relating to the damages and injuries caused by the R3 Acetabular System, including the optional metal liner or R3 metal liner are not subject to express or implied preemption pursuant to Section 360k of the MDA.

III. Plaintiff's request for leave to amend her complaint should have been granted

Plaintiff should have been given leave to amend her complaint to the extent that the Court found that plaintiff's Complaint was deemed insufficient to raise plausible facts upon which it could be determined that relief is warranted. The opportunity to amend would allow plaintiff to clearly plead that Smith & Nephew designed, marketed, distributed the R3 Acetabular System with an optional metal liner component and femoral head component, which were not PMA approved, and which were utilized in plaintiff's total hip replacement and proximately caused injury to plaintiff. Additionally, plaintiff's request would allow her to amplify factual allegations to the extent deemed necessary by the Court.

This Court reviews the District Court's denial of plaintiff's request for leave to amend under an "abuse of discretion" standard. *Panther Partners Inc.*, 347 Fed. Appx. 617. A district court has "abuse[d] its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence." *Cooter & Gell*, 496 U.S. at 405.

Courts "should freely give leave when justice so requires." Fed. R. Civ. P. 15 (a)(2). Courts of the State of New York have held that leave to amend should be freely and liberally granted. "Leave to amend, though liberally granted, may properly be denied for: undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed,

undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." *Ruotolo*, 514 F.3d at 191.

Plaintiff's Amended Complaint was the first instance that a complaint was before the District Court since plaintiff first amended her complaint following the removal of her action from the State Court to Federal Court. Allowing plaintiff the opportunity to amend this complaint would not be futile and it would be in the interests of justice to allow plaintiff a further opportunity to succinctly plead facts that directly tie Smith & Nephew with the decision to design the R3 Acetabular System in a manner that utilizes the R3 metal liner in conjunction with the metal femoral head component when in the course of a total hip replacement.

In this instance, the District Court abused its discretion in denying plaintiff's request for leave to amend. The District Court's denial was partly based upon an erroneous view of the evidence. The District Court misinterpreted the components of the product designed, marketed and distributed by Smith & Nephew, specifically the R3 metal liner and femoral head components for use in the R3 Acetabular System. The Court improperly relied upon the assumption that because the initial 510(k) approval of the R3 Acetabular System did not contain the R3 metal liner, that Smith & Nephew did not later design, market, and distribute the R3 metal liner as a component of the R3 Acetabular System.

In the decision and order related to plaintiff's Motion for Reconsideration, the District Court specifically indicated that leave to amend the complaint was denied on the basis of the Court's assessment that plaintiff's state law claims were preempted so that any proposed amendment would be futile. As addressed herein, plaintiff submits that any finding that plaintiff's claims were preempted in accordance with Section 360k (a) of the MDA was made in error.

Plaintiff submits that to the extent a further amplification of plaintiff's complaint is deemed necessary or appropriate, that the interests of justice are best served by permitted plaintiff leave to file an amended complaint.

CONCLUSION

The District Court's order dismissing plaintiff's claims for failure to state a claim and based upon preemption should be vacated and this matter should be remanded with instructions to defendant to serve a responsive answer. Alternatively, this matter should be remanded to allow plaintiff leave to file an Amended Complaint in this Action.

Respectfully submitted,

/s/ Michelle L. Pomerantz
MICHELLE L. POMERANTZ
Julien & Schlesinger, P.C.
207 East 94th Street, Suite 303
New York, NY 10128
(212) 962-8020

Counsel for Plaintiff-Appellant
Susan Simon

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 10,489 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman, font size 14.

Signed: /s/Michelle L. Pomerantz
Michelle L. Pomerantz
Attorney for Plaintiff

Dated: June 13, 2014